OCT 14 2011

Section 5.0 510(k) Summary

Administrative Information and Device Identification

Name and address of the manufacturer and sponsor of the 510(k) submission:	Manufacturer: Respironics 1001 Murry Ridge Lane Murrysville, PA 15668 Fax: (724) 387-4216 Sponsor: Respironics 1740 Golden Mile Highway Monroeville, PA 15146 Office: 724-387-7562 Fax: 724-387-7490
FDA registration number of the manufacturer of the new device:	2518422
Official contact person for all correspondence:	Joseph E. Olsavsky, RAC Sr. Manager - Regulatory Affairs Philips Respironics 1740 Golden Mile Highway Monroeville, PA 15146 Office: 724-387-7562 Fax: 724-387-7490 Email: joseph.olsavsky@philips.com
Date Prepared:	August 25th, 2011
Device Name:	Philips Respironics Trilogy Series Ventilators With the Masimo Oximetry Module
Proprietary name of new device:	Trilogy Oximetry Interface Kit
Common or usual name of the device:	Ventilator, continuous, life supporting
Philips/Respironics model number:	Respironics Trilogy Series Ventilators, Models 100, 200 and 202
Classification of new device:	Class II
Classification of the predicate device:	Class II
Classification Panel:	Anesthesiology
Panel Code:	CBK – ventilator, continuous, facility use NOU – ventilator, continuous, home use DQA – oximeter

CFR Regulation Number:	21 CFR 868.5895 Continuous ventilator a) *Identification.* A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device. (b) *Classification.* Class II (performance standards).
Predicate Device Name(s) and 510(k) numbers:	1. Versamed *i*Vent 201 Portable Ventilator with Pulse Oximeter (cleared under K061627 – date of concurrence: June 29, 2006) 2. Respironics Trilogy Series of Ventilatory Support Systems previously cleared under: - Trilogy 202 Ventilator - K093905 – date of concurrence: May 12, 2010. - Trilogy 200 Ventilator - K093416 – date of concurrence: January 29, 2010. - Trilogy 100 Ventilator - K083526 – date of concurrence: March 13, 2009.
Reason for submission:	Device modifications (to incorporate an oximetry accessory)

Description of Device:

The Respironics Trilogy Series Ventilators are mixed (dual) mode ventilators in that they provide both pressure support and volume modes of therapy. They are intended to provide therapy for a patient as he progresses through his disease state from non-invasive bi-level to invasive bi-level ventilation with an assured tidal volume. The Trilogy Series of Ventilators consist of three separate model configurations. These configurations are:

1. Trilogy 100 - a configuration that supports the Passive and Active w/ PAP exhalation device circuits (previously cleared under K083526).

2. Trilogy 200 - a configuration that supports the Passive, Active w/ PAP, Active w/ Flow circuit types (previously cleared under K093416).

3. Trilogy 202 (O2) - a configuration that supports the same circuit types and triggering changes as Trilogy 200 with the addition of oxygen (O2) blending capability .

The key benefits of this device are:

• Ease of use combined with clear presentation of detailed clinical information.
• Assist with patient lifestyle; internal battery & ruggedness facilitate mobility.
• Clinical data storage, transfer and reporting.
• Safety.
• Family series of devices with multiple modes and uses.
• Interface to humidifier for humidification therapy and increased patient comfort and convenience when used non-invasively.
• Single limb circuit.
• Active exhalation and/or passive exhalation circuit selection.
• Tidal volume (Vte) monitoring and alarm.
• Interface to O2 Blending Accessory that can blend oxygen from 21% to 100% (T202/O2).

The Trilogy Series of Ventilator are intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Trilogy is intended for adult and infant patients weighing at least 5 kg (11 lbs) with tidal volumes of at least 50ml and may be used for both invasive and non-invasive ventilation.

Trilogy is intended to be used in home, hospital and mobile applications such as wheelchairs and gurneys.

Operators of the device are expected to be: Patients, Lay caregivers (includes family members of patients and aides), Nurses, Respiratory therapists, Physicians and Home care providers.

The device is intended to provide an alarm system that sufficiently alerts the user if therapy cannot be provided.

The device is intended to:

- be man-portable and used by ambulatory and wheelchair bound patients.
- provide either continuous or intermittent ventilator support.
- have a clear and intuitive user interface for programming of prescriptions, monitoring patients, and responding to alarms.
- be easy to set up by the health care provider, requiring no special tools or instruments

The environment of use for the device will be for in the home, institutional, nursing, extended care, and clinical sleep lab settings. It can be used when attached to a wheelchair or on a gurney

or when transporting a wheelchair or gurney bound patient via an automobile while patient remains in wheelchair or gurney. The device is not intended to be used as a transport ventilator.

Description of the Trilogy Oximetry Interface Kit

The Philips Respironics Trilogy Series Ventilators with the Masimo Oximetry Module — the Trilogy Oximetry Interface Kit can be used with the Masimo Oximetry Module and the Respironics Trilogy Ventilators (listed below) to measure functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate for adult and pediatric patients. The Trilogy Oximetry Interface kit may be used in a home, institution and/or hospital environment.

Compatibility

The Trilogy Oximetry Interface kit is compatible with the following Philips Respironics Trilogy ventilators:

- Trilogy100
- Trilogy200
- TrilogyO2
- Trilogy202

The kit is compatible with the Masimo LNCS Series Sensor Accessories.

The Trilogy Oximetry Interface Kit consists of the following components:

- Masimo High Performance/Low Power Oximetry Module
- Masimo LNCS Series PULSE Oximeter Sensors (Disposable and Reusable)
- Trilogy Oximetry Interface Cable
- Trilogy Oximetry Interface Kit Instructions for Use

The Masimo High Performance/Low Power Oximetry Module, Interface Cable and Masimo LNCS Series PULSE Oximeter Sensors provide a non-invasive measurement of the oxygen saturation levels of hemoglobin. Data from the oximeter is transferred to the Trilogy Series

Ventilator Support System via the Cable. The oximetry status and data information is displayed in the top right corner of the Monitor Panel of the Trilogy device. This data is displayed on the device for patient monitoring and stored on the SD card in the Trilogy ventilator for use by Encore Pro and/or DirectView patient data management software.

Device Modifications:

The modifications to the Respironics Trilogy Series of Ventilatory Support Systems previously cleared under Trilogy 202 Ventilator – (K093905 – date of concurrence: May 12, 2010);

Trilogy 200 Ventilator – (K093416 – date of concurrence: January 29, 2010) and Trilogy 100 Ventilator – (K083526 – date of concurrence: March 13, 2009) consist of the addition an Oximetry Accessory. Specifically, the Trilogy Series Ventilators shall communicate with the Trilogy Interface Oximetry module via serial communication. The Trilogy Series Ventilators shall provide the necessary power to the Oximetry Interface Kit through serial interface and shall receive SPO2, Heart Rate, and Data Status information from the oximetry module.

Description of Oximetry Accessory

The product requirements document for the Trilogy Series ventilator states that:

- The ventilator shall communicate with the Masimo oximetry module (PN 1070183) via serial communication.
- The ventilator shall provide necessary power to oximetry through serial interface.
- The ventilator shall receive SPO2, Heart Rate, and Data Status information from the oximetry module.
- And provides a patient alarm for Low Oximetry SpO2 Alarm (when Oximetry module attached).

Alarm Description

1. Oximetry Low SpO2 Alarm
The ventilator shall generate a low SpO2 alarm when the SpO2 read from the oximetry module is less than the operator set low SpO2 setting. Low SpO2 setting only appears on the menu when the oximetry module is attached to the ventilator. The Low SpO2 Alarm shall terminate when the SpO2 reading is equal or greater than the Low SpO2 alarm setting for 3 seconds. The Low SpO2 Alarm shall generate a high priority alarm. Detection of a Low SpO2 alarm shall only occur after the ventilator verifies 3 continuous seconds of good data.

2. Loss of SpO2 Signal Alarm
The ventilator shall generate a Loss of SpO2 Signal Alarm if the Low SpO2 alarm is not OFF and the oximetry module is reporting questionable data or is disconnected for more than 10 seconds. Loss of SpO2 Signal alarm shall terminate after ventilator receives 3 continuous seconds of good data. The Loss of SpO2 Signal Alarm shall generate a high priority alarm. Detection of a Loss of SpO2 Signal alarm shall only occur after the ventilator verifies 3 continuous seconds of good data.

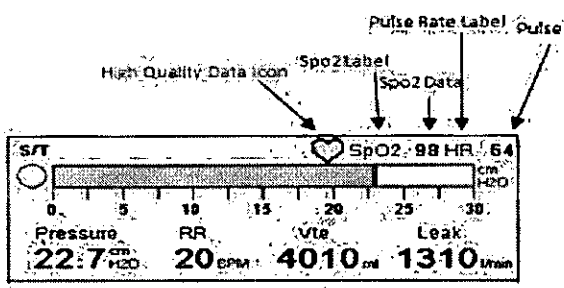
Oximetry Data

The Trilogy Series ventilator shall record SpO2 and Heart Rate data on the SD card from the oximeter accessory when the blower is on.

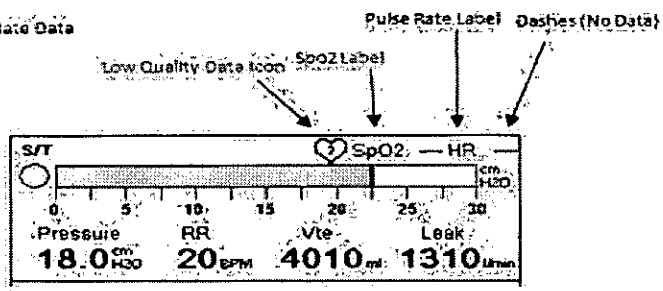
1. Oximetry SpO2% - When connected to the oximetry accessory, the ventilator shall display % SpO2 with a resolution of 1% and a range from 1 to 100%.

2. Oximetry Heart Rate - When connected to the oximetry accessory, the ventilator shall display the heart rate with a resolution of 1 Beats per Minute and a range from 25 to 240.
3. Oximetry Data Status - When connected to an oximetry module, the ventilator shall provide an indication that it is receiving valid or good data from the oximetry module. NOTE: Valid data is defined by the oximeter status.

When attached, the Oximetry Interface accessory is automatically detected by the device. When the accessory is detected by the device software and the blower is on, the module provides the status and data information, which is passed onto the user interface. The oximetry status and data information is displayed in the top right corner of the Monitor Panel in place of the date and time indicator. When the oximetry accessory is disconnected, the date and time indicator is displayed if detailed view is enabled. The oximetry status and data information is displayed regardless of the view option selected.



Monitor Panel High Quality Data



Monitor Panel Low Quality Data

The oximetry accessory status is categorized into two states:

	**High Quality Data**: The high quality data icon is displayed when the oximetry device and sensor are attached to the therapy device and patient correctly. The user interface displays a toggling heart icon, Spo2 and heart rate values
	**Low Quality Data**: A low quality data icon is displayed when the oximetry device is not functioning correctly or the sensor does not detect a patient. The user interface displays a heart with a question mark symbol. The Spo2 and heart rate values display dashes "---"

Comparison of Device Technological Characteristics to Predicate Device:

The submitted Respironics Trilogy Series Ventilator With Oximetry (i.e. the Trilogy Oximetry Interface Kit) has the following similarities to the predicate devices listed in this submission which previously received 510(k) concurrence; the Respironics Trilogy Series Ventilator With Oximetry (i.e. the Trilogy Oximetry Interface Kit):

- Has the same intended use – i.e., mechanical ventilator accessory intended for non-invasive monitoring of oxygen saturation and pulse rate,
- Uses the same operating principle,
- Incorporates the same basic ventilator system requirements including, but not limited to: physical interfaces; visual, audible and remote alarm system; modes of operation; & performance settings;
- Incorporates similar materials and
- Is manufactured utilizing the same manufacturing processes

According to FDA's Draft Reviewer Guidance for Premarket Notification Submissions - Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory, and Neurological Devices (November 1993), the following characteristics for the submitted device are identified:

- The Respironics Trilogy Series Ventilator With Oximetry (i.e. the Trilogy Oximetry Interface Kit) is not an implantable device.
- The Respironics Trilogy Series Ventilator With Oximetry (i.e. the Trilogy Oximetry Interface Kit) is intended for life support or life sustaining applications.
- The Respironics Trilogy Series Ventilator With Oximetry (i.e. the Trilogy Oximetry Interface Kit) is not sold as sterile.
- The Respironics Trilogy Series Ventilator With Oximetry (i.e. the Trilogy Oximetry Interface Kit) is not a single-patient-use device.
- The Respironics Trilogy Series Ventilator With Oximetry (i.e. the Trilogy Oximetry Interface Kit) must be prescribed by a physician.
- The Respironics Trilogy Series Ventilator With Oximetry (i.e. the Trilogy Oximetry Interface Kit) does not contain a drug or biological as a component.
- The Respironics Trilogy Series Ventilator With Oximetry (i.e. the Trilogy Oximetry Interface Kit) is not a kit.
- The Respironics Trilogy Series Ventilator With Oximetry (i.e. the Trilogy Oximetry Interface Kit) is software driven.
- The Respironics Trilogy Series Ventilator With Oximetry (i.e. the Trilogy Oximetry Interface Kit) is electrically operated.

All items addressed by the Reviewer's Checklist are unchanged from the predicate device identified in this submittal. See Section 12.0 – Substantial Equivalence Discussion for more detailed comparison of the subject device to the predicate devices identified in this submittal.

Statement of Intended Use:

The Trilogy Series of Ventilators (with or without the oximetry interface kit) are intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation with or without air/oxygen blending. Trilogy is intended for pediatric

through adult patients weighing at least 5 kg (11lbs). The Oximetry Interface kit is intended to measure functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate.

The device is intended to be used in the home, hospitals and institutions, and portable applications such as wheelchairs and gurneys. It may be used for both invasive and noninvasive ventilation. It is not intended to be used as a transport ventilator.

Compatibility

The Trilogy Oximetry Interface kit is compatible with the following Philips Respironics Trilogy ventilators:

- Trilogy100
- Trilogy200
- TrilogyO2
- Trilogy202

The kit is compatible with the Masimo LNCS Series Sensor Accessories.

Non-Clinical Testing:

This device has been tested to appropriate ISO, ASTM, and IEC standards and other applicable requirements passing all test protocols. The Respironics Trilogy Series Ventilator With Oximetry (i.e. the Trilogy Oximetry Interface Kit) was designed and tested according to guidance outlined in:

1. FDA's Draft Reviewer Guidance for Premarket Notification Submissions - Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory, and Neurological Devices (November 1993);

2. FDA's Draft Reviewer Guidance for Ventilators July 1995;

3. Draft Guidance for Industry and FDA Staff - Pulse Oximeters - Premarket Notification Submissions [510(k)s] (July 19, 2007); and

4. FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005).

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the Respironics Trilogy Series Ventilator With Oximetry complies with the following voluntary standards.

<u>List of standards and guidance documents recognized by FDA to establish a basis for safety and effectiveness for the Trilogy Ventilator Series With Oximetry Device:</u>

1. AAMI/ANSI/ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing.

2. IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety.

3. IEC 60601-1-2 Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

4. IEC 60601-1-8 Ed. 1, Medical electrical equipment - Part 1-8: General requirements for safety - Collateral Standard: Alarm Systems - Requirements, tests and guidances - General requirements and guidelines for alarm systems in medical equipment.

5. IEC 62304 Medical device software - Software life cycle processes.

6. IEC 60601-2-12 Medical electrical equipment – Part 2-12: Particular requirements for the safety of lung ventilators – Critical Care Ventilators.

7. ASTM F1246 Standard Specification for Electrically Powered Ventilators, Part 1 – Positive Pressure Ventilators and Ventilator Circuits.

8. ISO 14971 Medical devices - Application of risk management to medical devices.

9. IEC 68-2-6 Environmental Testing – Part 2: Tests – Test Fc: Vibration (sinusoidal).

10. IEC 68-2-27 Environmental Testing – Part 2: Tests – Test Ea and guidance: Shock.

11. IEC 68-2-34 Environmental Testing – Part 2: Tests – Test Fd: Random Vibration Wide Band.

12. IEC 60601-1-4 Medical Electrical Equipment Part 1: General Requirements for Safety. Part 4. Programmable Electrical Medical Systems

13. ISO 9919 Medical electrical equipment -- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

14. IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

The non clinical testing results provide assurance that the device meets its specifications and is safe and effective for its intended use. The Respironics Trilogy Series Ventilator With Oximetry (i.e. the Trilogy Oximetry Interface Kit) met the required performance criteria and functioned as intended.

See Section 16.3 Traceability Analysis, Section 16.4 Verification and Validation Testing Documentation, Section 17.0 Electromagnetic Compatibility and Electrical Safety, Section 18.0

Performance Testing - Bench and Attachment B – Trilogy Ventilator Product Requirements Document.

Statement of Safety and Effectiveness:

Analysis of comparison of design, function and features of the Respironics Trilogy Series Ventilator With Oximetry (i.e. the Trilogy Oximetry Interface Kit) to the predicate devices:

1. Versamed *i*Vent 201 Portable Ventilator with Pulse Oximeter (cleared under K061627 – date of concurrence: June 29, 2006)

2. Respironics Trilogy Series of Ventilatory Support Systems previously cleared under:

Trilogy 202 Ventilator - K093905 – date of concurrence: May 12, 2010
Trilogy 200 Ventilator - K093416 – date of concurrence: January 29, 2010
Trilogy 100 Ventilator - K083526 – date of concurrence: March 13, 2009

and together with the results of testing demonstrates the device to be substantially equivalent to the predicate devices in terms of meeting performance criteria and functioning as intended.

Conclusion:

The Respironics Trilogy Series Ventilator With Oximetry (i.e. the Trilogy Oximetry Interface Kit) is substantially equivalent to the predicate devices listed in this Summary and the device, as changed, does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Philips Respironics, Incorporated
Mr. Joseph E. Olsavsky
Senior Manager - HRC Regulatory Affairs
Sleep & Home Respiratory Care
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

OCT 1 4 2011

Re: K111610
Trade/Device Name: Philips Respironics Trilogy Series Ventilators with the Masimo Oximetry Module
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK, NOU, DQA
Dated: October 6, 2011
Received: October 7, 2011

Dear Mr. Olsavsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4.0 Indications for Use

Indications for Use

510(k) Number (if known): K111610

Device Name: Philips Respironics Trilogy Series Ventilators with the Masimo Oximetry Module

The Trilogy Series of Ventilators (with or without the oximetry interface kit) are intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation with or without air/oxygen blending. Trilogy is intended for pediatric through adult patients weighing at least 5 kg (11lbs). The Oximetry Interface kit is intended to measure functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate.

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- Trilogy100
- Trilogy200
- TrilogyO2
- Trilogy202

The kit is compatible with the Masimo LNCS Series Sensor Accessories

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111610

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schuller

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K 111 610